STATUS OF CLAIMS

Claims 1-20 are presently pending in the application. Claims 1, 6, 19, and 20 have been amended. Support for the amendment to these claims is provided in the as-filed specification and claims and particularly, in paragraph [0002] of the specification and accompanying figures.

REMARKS

Objection to Drawings

In the Office Action, the Examiner objects to the drawings as failing to show every feature of the invention specified in the claims. Specifically, the Examiner requests Applicant to show "two valve seats, the first position, the second position, and the default neutral position of the valve" in the drawings or to cancel the features from the claims.

In response, Applicant traverses the objection and states that the Examiner's objection is erroneous. However, to facilitate the prosecution of the application, Applicant hereby submits drawings that are in compliance with 37 C.F.R. 1.83(a) and which do not introduce new matter.

Applicant provides FIGS. 18A-18C which further illustrate the two valve diaphragm seals and valve seals with respect to the device of the present invention in each of the three positions: 1) default neutral position with both valve seats open (FIG. 18A); 2) left valve seat (86a) is open and right valve seat (86b) is closed (FIG. 18B); and 3) left valve seat (86a) is closed and right valve seat (86b) is open (FIG. 18C). Further, FIG. 18A depicts a blow-up view of detail E in FIG 11, with the device of the invention in a default neutral state and a close-up detail, L, showing an opening for fluid passage between the valve diaphragm seal and the valve seat. As shown in FIG. 18A, at a default neutral position when the device is not pneumatically actuated, there exists an opening between the valve diaphragm seals and the valve seats to create a fluid passage between these two elements. When pneumatically actuated from either side, the flexible valve diaphragm seal is deformed such that valve diaphragm seal is pushed into direct contact with the valve seat and the fluid passage between these two elements is closed.

In addition, Applicant provides the following arguments to support its traversal of the rejection. The Examiner erroneously states that "a schematic drawing cannot represent the open and closed positions of the valve when only details of relative positions of the internal parts and features of the valve can clearly show the respective positions." Applicant respectfully disagrees. 37 C.F.R. 1.83(a) clearly states that features disclosed in the description and claims,

where their detailed illustration is not essential for a proper understanding of the invention, ***should*** be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation (e.g., a labeled rectangular box). In this regard, it is respectfully submitted that one of ordinary skill in the art would readily understand the three possible positions of the valve that is described and claimed herein, for example, by following the instructions in the specification regarding the construction of such a valve. The valve according to one embodiment, is exemplified, for example, in Figure 9 and the valve in the first position, second position, and default position are illustrated, for example, in FIGS. 17A, 17B, and 17C, respectively, in the form of a labeled representation in accordance with 37 C.F.R. 1.83(a). One of skill in the art would readily understand that the valve 1) can be pneumatically operated to open the first valve seat while closing the second valve seat, 2) can be pneumatically operated to close the first valve seat while opening the second valve seat, or 3) can occupy a central position where the first and second valve seats are open (the default neutral position) when supply pressure operating the valve is removed. Further details are provided in the discussion to follow regarding 35 U.S.C. § 112, first paragraph.

Rejection Under 35 U.S.C. §112, first paragraph

In the Office Action, the Examiner maintained his rejection of claims 2, 4, 11 and 19 under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. Specifically, the Examiner states that the "Examiner is unsure as to how the valve returns to its neutral state without the use of a spring return mechanism. If the valve is in a closed position, and the pneumatic forces are removed from both pneumatic ports simultaneously, how does the valve member move from the closed position to the open position without the use of a spring return mechanism?"

In response, Applicant respectfully traverses the rejection under 112, first paragraph and its accompanying remarks. Applicant states that Examiner's enablement rejection is legally improper and furthermore, is based on his lack of fundamental understanding of the mechanical nature of Applicant's device and is not based on a lack of teaching within the disclosure of how to make and to use the invention of the claims. Applicant has repeatedly pointed out to the Examiner all of the teachings in the specification that support the double pneumatic acting valve

of the present invention. The fact that the Examiner, himself, lacks clarity about the valve mechanism of the present invention is not a proper legal basis for an enablement rejection.

The following is a well-established PTO procedure, based on the statute and legal precedent:

> A specification disclosure which contains a teaching of the near and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented ***must*** be taken as in compliance with the enabling requirement of the first paragraph of section 112 unless there is ***reason to doubt the objective truth of the statements contained therein which must be relied upon for enabling support.***

MPEP 2164.04 (emphasis added)(citing *In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (CCPA 1971).

The Examiner has put forth no ***reason to doubt*** that the detailed teachings and instructions in the specification will yield a valve having a default neutral state in which all valve seats of the three-way valve remain open when a supply pressure operating the valve is removed. In the absence of evidence or prior art, the Examiner has not satisfied the burden of providing such reason to doubt the object truth of the statements in Applicant's specification.

Rather than providing any proof, the Examiner poses questions. For example, in the Final Office Action, the Examiner poses:

> If the valve has one valve seat "open" and one valve seat "closed," an the supply pressure is removed form [sic] that "closed" valve seat, what is forcing the [sic] that particular valve seat to automatically go back to the "open" position? Is it not going to go back to the "open" position all by itself. It needs some sort of force acting on it to move it form [sic] the "closed" position back to the "open" position. If the valve seat moves back to its "open" position by a force of a pneumatic return, then how does the valve go to the default neutral state when the supply pressure is removed?

(page 5, first full paragraph, Final Office Action)

Applicant states that the above indicates that the Examiner appears to take the position that although there the disclosure teaches ***how to make*** the three-way valve of the present invention, the specification somehow fails to show ***how the valve works.*** However, "it is ***not*** a requirement of patentability that an inventor correctly set forth, or even know, ***how or why the invention works.***" *Newman v. Quigg*, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989)(emphasis added); *see also Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570, 219 USPQ 1137, 1140 (Fed. Cir. 1983)("[I]t is

axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests.") Even though it is not required, the specification explains how and why the invention works.

In the DETAILED DESCRIPTION of the specification, Applicant provides not only the structure of the new three-way valve of the present invention (Figure 9), but also provides details regarding a simply method of manufacture of such a device, based on an existing three-way valve and provides illustrative drawings of both the prior art and the improved valve of the present invention. *See* paragraphs [0032] to [0033] and [0040] to [0043].

Applicant has previously explained to the Examiner in great detail how the valve returns to its neutral state without the use of a spring return mechanism. Specifically, Applicant has drawn the Examiner's attention to the default structure of Applicant's device in contrast to prior art three-way valves. In the prior art Takasago three-way valve of Figures 2-8, due to the presence of the spring return in the valve (see Figure 5), there is ***always an actuating force on the valve, even when the supply pressure operating the valve is removed, e.g., when the valve is not in use*** (see paragraph [0002] of the Background and see also the October 10, 2006 Amendment and Response in which Applicant describes in great detail the mechanics of the Takasago valve with a spring return).

The prior art Takasago three-way valve, as can be seen from FIG 5 (prior art), provided below with annotations, is a pneumatically activated valve (via pneumatically activated plunger 63) with a spring return 61.

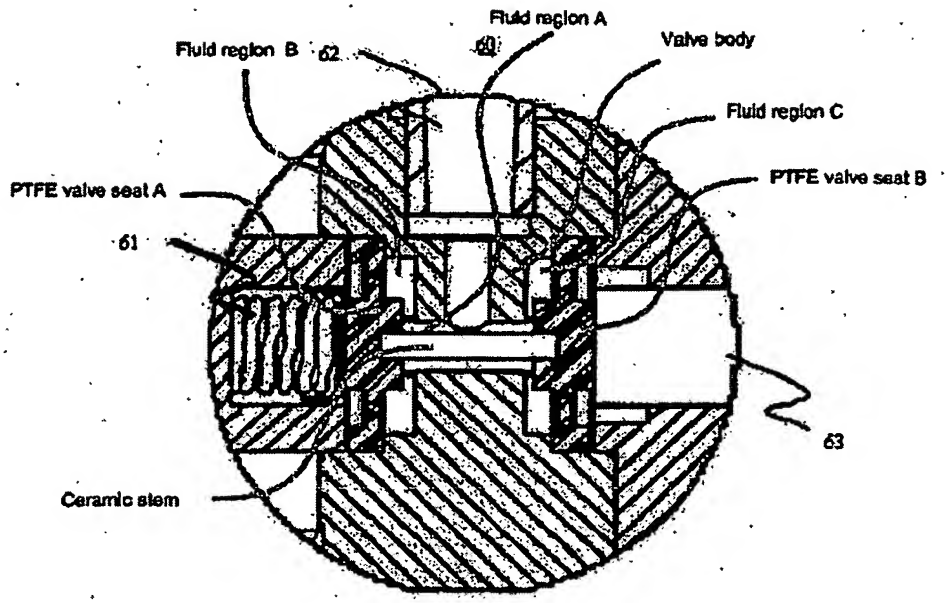

Fig. 5

The valve contains an assembly that includes two PTFE valve diaphragm seals mechanically interlocked with a small ceramic stem ("the Takasago assembly"). As can be seen from FIG 5, the PTFE valve diaphragm seals are ***fixed*** such that they cannot move horizontally without deformation. Moreover, the PTFE diaphragm seals are elastic and in the absence of any horizontal force (i.e., pneumatic force or spring force), would be centered with respect to the valve body (which is shown in right-hand downward cross-hatching) such that a gap is created between the valve diaphragm seals and the valve seats such that both valve seats are ***open***. However, when the plunger 63 of FIG 5 is pneumatically activated, it drives the assembly to the left. This overcomes the force being exerted by the spring return 61 and allows the PTFE valve seat A to pull away from the valve body, resulting in fluid communication between fluid region A (which is connected to a first common port) and fluid region B (which is connected to a second port). This also pushes the PTFE valve diaphragm seal B against the valve seat of the valve body, precluding fluid communication between fluid region A and fluid region C (which is connected to a third port). On the other hand, when the pneumatic pressure is ***removed***, the assembly is driven to the ***right*** by the spring return 61, forcing the PTFE valve diaphragm seal A against the valve seat of the valve body, and preventing fluid communication between fluid region A and fluid region B. The PTFE valve diaphragm seal B, on the other hand, is pulled

away from the valve body, allowing fluid communication between fluid region A and fluid region C. Thus, due to the presence of the spring return in the valve of FIG 5, there is ***always an actuating force***, even when the supply pressure operating the valve is removed (e.g., when the valve is not in use). Consequently, there is never a situation in which the assembly is not being urged to left or right, and thus the assembly is never allowed to become centered with respect to the valve body (due to the elastic rebound of the PTFE material). As such, there is never a situation where both valve diaphragm seals are open causing a gap opening between the seals and the valve seats (i.e., at its "equilibrium" position). Moreover, when the supply pressure operating the valve is removed from the valve of FIG 5, the PTFE valve A is forced against the valve body by the spring return, and many times results in the valve becoming glued shut in this position.

All of the above is in contrast to the present invention which is mechanically configured such that "all valve seats of the medical device [are] ***open*** when the unit is not in use." (paragraph [0005]) (emphasis added). Referring to Figure 9, which shows an embodiment of the present invention, the three-way valve of the present invention has two ends, which remain open when the unit is not in use, i.e., unit is in a default neutral state. Both valve seats are pneumatically driven and there is no spring return. Thus, when the pneumatic force is removed from the valve (e.g., when the valve is not in use), the assembly is neither forced to the left nor to the right, allowing the assembly to return to its centered "equilibrium" position when both valve seats are open. This completely opens the valve (i.e., establishing fluid communication between fluid region A and fluid region B at the same time as establishing fluid communication between fluid region A and fluid region C). More importantly, when the spray coat machine of the present invention is not in use, ***neither valve seat is held closed, which eliminates the possibility of the valve becoming glued shut.*** See paragraph [0033].

As described in the specification with respect to Figure 9, "[F]our millimeter tubing 71 connects to ***one end*** of the three-way valve, which is coupled to a nitrogen source for controlling the valve. Six millimeter tubing 74 connects to the ***other end*** of the three-way valve, which is also coupled to a nitrogen source for controlling the valve. According to one aspect of the present invention, when the nitrogen pressure is removed, a ***default neutral state*** is achieved in which ***both valve seats of the three-way valve are open***, thereby preventing solids buildup or gluing of the valve seats closed by drying agents. Three valve ports are available 73, 75 and 76

for use to couple to a reservoir, a spray nozzle and syringe, or other applications requiring three valves." (emphasis added) (paragraph [0025]).

Turning now to the Examiner's question regarding "how the valve returns to its neutral state without the use of a spring return mechanism," Applicant states that the spring return mechanism is not necessary because Applicant's device contains a second pneumatic return. As shown in Figure 11, Applicant's device is mechanically structured so as "to make the valve 70 operate with a second pneumatic return rather than a spring return mechanism." Thus, where a spring return mechanism would normally be located, Applicant's device provides a second pneumatic return. Instead of the spring return mechanism, the device provides other structural elements that allow the device to still function without such spring return mechanism. This is achieved in Applicant's invention, for example, by adding the elements shown outside the "box" illustrated in Figure 11: "a plunger 77 is added along with an air pressure diaphragm 78, a modified valve bracket 30, and a 6-millimeter tubing interconnection 74." (paragraph [0032]). Because the valve is fully pneumatically driven, when the pneumatic force is removed from the valve (e.g., when the valve is not in use), the assembly of valve diaphragm seals and valve seats interlocked with a small ceramic stem is neither forced to the right nor to the left, allowing the assembly to return to its centered "equilibrium" position wherein no pressure/energy is exerted. A great advantage of having a device where the valve seats of the three-way valve are open in a default neutral state is that it prevents the possibility of the valve becoming glued shut by drying agents, which has been a problem in prior art valves wherein the valve seat is closed in its neutral state (paragraph [0025]).

A overview of the types of changes that would be need to be made from a prior art Takasago three-way valve to result in Applicant's invention is provided in paragraph [0010], which states that it entails "disassembling a first symmetric three-way valve and reassembling the first valve backwards, and replacing a spring return of a second identical valve with the backwards-assembled first valve. In addition, the method includes attaching the backwards-assembled first valve to a valve body of the second valve using a bracket from the second valve, as well as drilling out and counter boring two tapped holes in a valve bracket and using the valve bracket to attaching the pneumatic plunger portion from the first valve to a valve body of the second valve."

Applicant states that one of ordinary skill in the art would be enabled to make and to use the invention of the claims based upon the prior art Takasago three-way valve and the detailed instructions provided by Applicant in the specification, claims and drawings, to make the changes and modifications to transform the prior art Takasago three-way valve to the device of the present invention. In light of the above, reconsideration and withdrawal of the rejection of claims 2, 4, 11 and 19 under 35 U.S.C. §112, first paragraph, is requested.

Rejection Under 35 U.S.C. §103(a) – Kintner and acknowledged state of the art

Claims 2, 4, 5, 7, 10-13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the acknowledged prior art of Figure 1 in view of Kintner (U.S. Patent No. 3,426,799). Claims 1, 3, 6, and 14-20 are rejected as being unpatentable in light of acknowledged prior art of figure 1-8, in view of Kintner.

In response, Applicant respectfully traverses the rejection and its accompanying remarks. Applicant asserts that the Examiner has not satisfied his burden of establishing a *prima facie* case of obviousness based upon the prior art.

The Examiner asserts that applicant's admitted prior art of Figure 1 (everything but the valve 70) in combination with the valve of Kintner, teaches the claimed invention. Specifically, the Examiner asserts that while "the admitted prior art does not specifically disclose that the valve is a pneumatically actuated three-way valve with no spring return mechanism and two valve seats. However, Kintner shows a pneumatic actuated valve (figures 1 and 2) and a three-way valve (figure 3), both having no spring return mechanism....It would have been obvious to...substitute the new pneumatically actuated three-way valve of Kintner for the three-way valve of figure 1 in order to make the medical device operate more precisely by having a pneumatic return mechanism that can be adjusted."

The Examiner's primary argument appears to be that Figure 1 of Kintner teaches all of the elements of the invention of independent claim 1 except that it fails to teach "that the valve is a pneumatically actuated three-way valve with no spring return mechanism and two valve seats." To remedy such deficiency, the Examiner then turns to Kintner, a 1969 patent document for an "Automatic Valve." However, Kintner fails as a primary reference. The valve of Kintner simply does not disclose a dual pneumatic actuated three-way valve comprising two air pressure diaphragms and two valve seats that is dual actuated with no spring return mechanism.

Upon reviewing the valve device of Kintner in detail, it becomes apparent why the device of Kintner fails to teach the claimed invention and why the combination with the acknowledged prior art fails to establish a *prima facie* case of obviousness. Kintner expressly ***teaches away*** from valves such as those of the present invention that include air pressure diaphragms and valve seats, dismissing them as undesirable. Instead of valves having seats and diaphragms, Kintner advocates a valve actuated by a "piston which can be moved by application of extremely small pressures to operate the valve" and which dispenses with the need for "costly stems, and unreliable seats and diaphragms." (col.1, lines 7-15).

Entirely different in its mechanism from the valves of the present invention, the Kintner valve involves a sliding piston assembly that moves from a default closed "seated position" to an "open position." Specifically, Kintner teaches "floating O-rings" wrapped around a series of pistons that are mounted on piston rods. In its default state, as shown in Fig. 1 of Kintner, the valve is in the "closed position." (col. 1, lines 35-37). Then, "[i]n operation, the O-ring actually "floats" radially outwardly as it moves from the position shown in Fig. 1 to that shown in Fig. 2 since the stretched O-ring leaves its seating position during such movement as it slides across the recessed area 16 in the flow stream. Line pressures immediately encapsulate the O-ring." (col. 2, lines 48-66).

Thus, even if one of skill in the art were assumed to be motivated to combine Kintner with the acknowledged prior art, which he would not, the result would not be the present invention. There is nothing to support the assertion that the piston-valve of Kintner could result in the claimed three-way valve having "a default neutral state in which all valve seats of said three-way valve remain open when supply pressure operating said valve is removed." Without any type of force to move the piston, the valve of Kintner would remain in the closed position as discussed above. The Examiner has not shown otherwise.

Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *In re Kahn,* 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in, KSR Int'l v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740-41, 82 USPQ 1385, 1396 (2007). Applicant respectfully states that the Examiner has neither met his burden of establishing a *prima facie* case of obviousness nor provided a rational underpinning to support his legal conclusion of obviousness.

As the Kintner reference, either singly or in combination with the acknowledged prior art, fails to establish a *prima facie* case of obviousness, reconsideration and withdrawal of the rejection as being unpatentable over the cited art, is therefore requested.

Applicant also reiterates the remarks presented in Applicant's response filed October 10, 2006 and March 26, 2007 for the rejection of the claims over Kintner and acknowledged prior art. For at least these reasons, it is respectfully submitted that the rejected claims are patentable over the cited references.

Rejection Under 35 U.S.C. §103(a) – Liston and Kintner

Claims 1-7 and 10-20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Liston (U.S. Pat. No. 3,817,425) in view of Kintner. This rejection is respectfully traversed.

Liston fails to correct the deficiency of Kintner, as discussed above. All presently pending claims require a dual pneumatic actuated three-way valve comprising two valve seats. Kintner, on the other hand, does not teach such a valve but rather, teaches piston-operated valves. It is respectfully requested that the remarks presented in Applicant's response filed October 10, 2006 and March 26, 2007 be herein incorporated by reference.

Rejection Under 35 U.S.C. §103(a) – Acknowledged prior art, Liston and Chemline Plastics

Claims 8-9 have been rejected under 35 U.S.C. §103(a) as being unpatentable over acknowledged prior art, in view of Kintner, further in view of Chemline Plastics (2001). This rejection is respectfully traversed. Independent claim 5, upon which claims 8-9 depend, is patentable for the reasons discussed above and the rejection of claims 8-9 fails for the same fundamental reasons and in addition, these claims provide further distinguishing features.

CONCLUSION

Applicants respectfully submit that all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite the application at large, request is made that the Examiner telephone the undersigned attorney at (908) 518-7700, ext. 7 in order to resolve any outstanding issues.

Dated: July 21, 2009

Respectfully submitted,

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Attachment

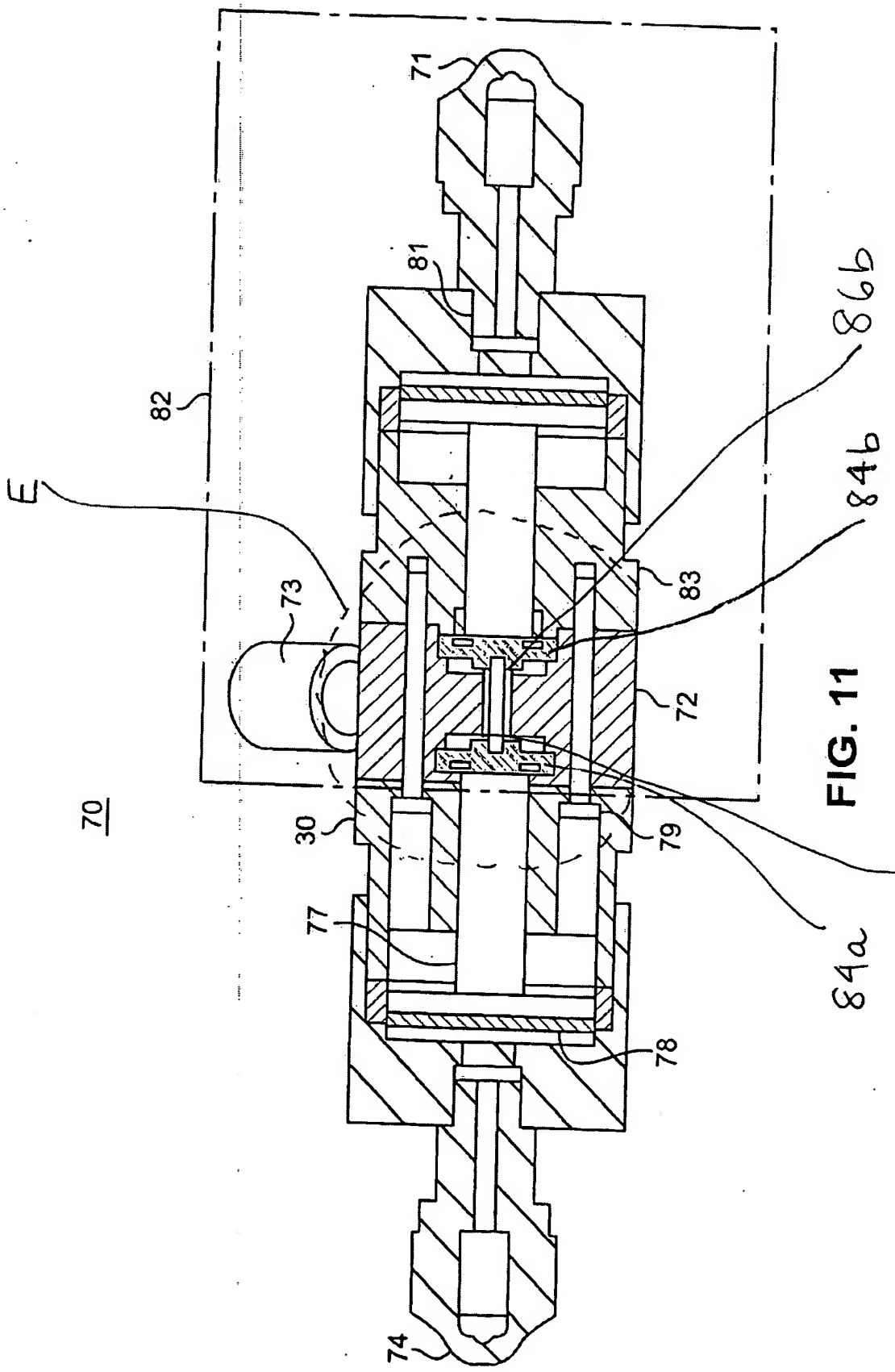

FIG. 11